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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,224	02/12/2004	Gustav Gaudernack	1702.4015LO	2068
5514	7590	12/05/2005	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO			BORIN, MICHAEL L	
30 ROCKEFELLER PLAZA			ART UNIT	
NEW YORK, NY 10112			PAPER NUMBER	

1631

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,224	Applicant(s) GAUDERNACK ET AL.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-32 are currently pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-14, drawn to peptides and compositions thereof.

Claim 14 of this Group is further divided into following Groups:

Groups I.1-I.60 drawn to different peptides derived from unrelated genes as listed in claim 11.

Upon selection of one of the Groups from Groups I.1-I.60, claims 1- 10,12-14 will be addressed as linking claims.

Further, see "***Sequence Election Requirement Applicable to All Groups***" below.

II¹. Claim 15, drawn to vaccine.

III¹. Claim 16, drawn to method of use of protein of Group I for making pharmaceuticals.

¹All groups reciting product of Group 1 are subject to restriction to groups .1-~~60~~ similarly to product of Group I.

- IV¹. Claim 17,18, drawn to method of use of protein of Group I for vaccination
- V¹. Claim 19,20, drawn to method of use of protein of Group I for treatment of cancer.
- VI¹. Claim 21, drawn to composition comprising other active ingredients in addition to protein of Group I.
- VII. Claims 24-26,29,30, drawn to DNA.
- VIII. Claims 27,31, drawn to method of use of DNA of Group VII for making pharmaceuticals.
- IX. Claims 28,32 (in part), drawn to *in vivo* treatment of cancer.
- X. Claim 28,32 (in part), drawn to *in vitro* treatment of cancer.
- XI. Claims 22,23, drawn to method of identifying new peptides.

The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is the technical feature that links Groups I-X. Group I is not the contribution over the prior art because it is suggested by references cited in the International Search report issued in the preceding PCT case, as well as by plurality of references teaching peptide fragments. Therefore, the lack of unity is present because the linking technical feature is not a "special technical feature" as defined by PCT Rule 13.2.

Group I and II are drawn to patentably distinct products which require differing characteristics. The vaccine composition requires different host, not required for polypeptide of Group I, has different pharmaceutical effect, and has separate enablement requirement.

Groups I.1-I.60 are drawn to peptides derived from unrelated genes, which peptides are independent and patentably distinct compounds since each of these compounds possess different structure, and/or physico-chemical properties, and capable of separate manufacture and/or use. The correspondent methods of use are independent and/or distinct due to the use of different patentably distinct agents

Group VI is drawn to pharmaceutical composition comprising active agents not required in composition comprising protein of Group I. Accordingly, this group will require separate search and considerations.

Groups I and VII are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group I, the critical feature is a polypeptide whereas for Group VII the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group I to be directed as to its synthesis by a polynucleotide of Group VII, however, the completely separate chemical types of the inventions of Groups I and VII supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Groups III-V are drawn to distinct processes of using the product of Group I. The processes of groups III-V are distinct because the processes are not disclosed as usable together, and because none of the processes reasonably suggest the other two.

Similarly, Groups VIII-X are drawn to distinct processes of using the product of Group VII. The processes of the groups are distinct because the processes are not disclosed as usable together, and because none of the processes reasonably suggest the other two.

Further, the method of Group XI is unrelated to the product of Groups I,II,VI, or VII as it does not utilize said products. Also, the method is distinct from methods of Groups III-V, VIII-X, as the processes are not disclosed as usable together.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on a plurality of independent and/or patentably distinct sequences. Each peptide or nucleic acid sequence is independent and/or patentably distinct because they are unrelated compounds, there is no disclosed core structure required for a common utility, and because each of these compounds possess different structure and/or physico-chemical properties, and/or capable of separate manufacture and/or use. **For an elected Group the Applicants must further elect a single amino acid or nucleic acid sequence, such as those recited in claims 1 or 26,27. This is not an election of species requirement.**

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Examination will be restricted only to a Group drawn to elected sequences.

Because these inventions are distinct for the reasons given above, and because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'Michael Borin', with a long, sweeping horizontal line extending to the right.

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb